IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of: Richard J. Lazzara, et al.	Confirmation No. 7280
Application No. 09/237,605	Art Unit: 3774
Filed: January 25, 1999	Examiner: Paul B. Prebilic
For: Infection-Blocking Dental Implant	Customer No. 70001

Mail Stop Appeal Brief – Patents – via EFS Web
Commissioner for Patents
Alexandria, Virginia 22313-1450

TRANSMITTAL OF REPLY BRIEF

Dear Commissioner:

Submitted herewith is the Appellants' Reply Brief Pursuant to 37 C.F.R. § 41.41 responsive to Examiner's Answer mailed on September 1, 2009. The due date for the Reply Brief is two months from the mailing date of Examiner's Answer and this paper is being timely filed within that time period on the next business day.

It is believed that no fees are presently due; however, should any fees be required – except for payment of the issue fee – or should any credits for overpayment be due, the Commissioner is authorized to charge or credit Nixon Peabody LLP Deposit Account No. 50-4181 (247168-000035USC1).

Respectfully submitted,

Dated: November 2, 2009

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REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.37

Dear Commissioner:

This Reply Brief is responsive to the Examiner's Answer, mailed on September 1, 2009, in the Appellants' appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 51 and 60-75 in the above-referenced application. This Reply Brief supplements the arguments presented in the Appeal Brief filed by the Appellants on May 26, 2009 ("Appeal Brief").

1. Formalities Regarding the Gubbi Declaration Photographs

At the outset, the Appellants are attaching a cleaner version of the Gubbi Declaration having cover pages separating Exhibits A, B, C, and D. The photographs accompanying the Gubbi Declaration were originally submitted in color on June 26, 2003, and the USPTO PAIR website reflects that such color photos are in the file. Even the Examiner's Answer cites to the artifact folder color micrographs of Gubbi. Examiner's Answer, page 5. The original color copies submitted on June 26, 2003 are believed to be the best copies and are, thus, attached now for convenience. Specifically, the Appellants note that these color versions are believed to be clearer than the relatively dark black-and-white photographs. For example, the labeling on the bottom left-hand corners of, e.g., Comparative Example 1 and Example 3 of Exhibit B of the Gubbi Declaration can be more clearly viewed in the color versions.

The Appellants note that the Gubbi Declaration and the photographs appended thereto were first submitted to the Examiner on June 26, 2003 in response to an office action dated March 26, 2003. The subsequent three office actions (dated October 7, 2003, July 23, 2004, February 7, 2008) were silent regarding any deficiencies in the photographs. Likewise, the Examiner did not mention any such deficiencies during an interview with the Appellants conducted on November 18, 2004 or the Examiner's answer (dated April 5, 2006) submitted during the previous appeal. In fact, it was not until nearly five-and-a-half years after the photographs were originally submitted that the Examiner (in the Final Office Action Dated October 21, 2008) finally objected that "the photographs [submitted with the Gubbi Declaration] are of poor quality such that little detail can be ascertained therefrom." See Ex. 2, page 4. This objection has been reiterated in the current Examiner's Answer. See Examiner's Answer, page 5. Not only is such delay by the Examiner undue and unjustified, but it is without merit, especially given the reproduction of the one-page comparison of selected photographs (Ex. 9)

submitted with the Appellants' Appeal Brief on May 26, 2009 and the Examiner's own reliance on the photographs of Exhibits A and B of Exhibit 1 of the Gubbi Declaration in concluding that "the prior art treatments do result in cone-shaped elements." Examiner's Answer, page 5.

The Examiner also states that it is not clear how the photographs of Haruyuki (labeled Photo 1, Photo 2, Photo 3, Photo 4, etc.) correspond to the Appellants' use of "Figure 2" and "Figure 4" in Exhibit 9. Examiner's Answer, page 6. The Appellants note that the translation of Haruyuki itself interchangeably uses the terms "pictures" (see Ex. 5, page 6), "figures" (see, id., page 7), and "photos" (see, id., page 8). Thus, it is believed to be evident and understood that Appellants' use of "Haruyuki Fig. 2" in Exhibit 9 corresponds with Haruyuki's "Photo 2" and Appellant's use of "Haruyuki Fig. 4" corresponds with Haruyuki's "Photo 4."

Thus, the Appellants believe that the photographs submitted with the Gubbi Declaration (Ex. 8) and the one-page comparison including selected photographs from the Gubbi Declaration (Ex. 9) are satisfactory and persuasive.

2. The Argument in the Examiner's Answer that Haruyuki's Surface Inherently Meets Claimed Acid-Etched Surface Is Misplaced

The independent claims call for various structural features of the claimed dental implant, such as the "head portion", "the lowermost end", "non-rotational features within the head portion," "the threaded portion", "the cylindrical section of the threaded portion", "the tapered section of the threaded portion", "the self-tapping region", as well as the location of the acid-etched surface relative to these other components. The final rejection does not rely on Haruyuki to teach any of these structural features of the claimed dental implant. Rather, the final rejection and the Examiner's Answer rely on Haruyuki for the teaching of the acid-etched surface. The question is – does Haruyuki teach the claimed acid-etched surface?

Independent claim 1 recites a surface in which "said roughened region [is] uniformly acid-etched with a second acid solution . . ." and "said roughened region including an array of

irregularities having peak to valley heights not greater than about 10 microns." Dependent claim 62, which depends on independent claim 1, calls for the irregularities to include "cone-shaped elements."

Independent claim 63 recites a threaded portion having "an acid-etched surface . . . ," "said acid-etched surface having an array of irregularities having peak-to-valley heights not greater than about 10 microns," and "said irregularities including cone-shaped elements."

Independent claim 68 calls for the threaded portion to have "an acid-etched surface . . ." and "said acid-etched surface having an array of irregularities having peak-to-valley heights not greater than about 10 microns," and "said irregularities including cone-shaped elements."

Haruyuki does not disclose an acid-etching treatment that roughens the surface after the native oxide has been removed. See Ex. 5, page 4, column 2. As explained in the Appeal Brief, the Applicants believe that there is a structural surface difference between the claimed surface and Haruyuki's surfaces that can be seen from Haruyuki's photographs, perhaps due to the fact that Haruyuki smoothens its roughened surface and the Appellants further roughen their surface. See Ex. 8 (Ex. B); Ex. 9; Ex. 5, page 4. Haruyuki describes his surface as having "pits" or "micro fine pits" with certain "pore sizes" after the pre-treatment using the HF concentration. Ex. 5, pages 3-4. Haruyuki describes the need for his post-treatment of HF and H_2O_2 "to smooth the sharp edges and pointed ends formed on the ridgelines of the micro fine pits generated during the pretreatment." Ex. 5, page 4. As such, Haruyuki describes his surface as being pitted and including smoothened ridgeline structures around the pits. Haruyuki's photos of his surface seem to show this pitted surface.

Independent claims 63 and 68 (and dependent claim 62 stemming from independent claim 51) recite acid-etched surfaces having an array of irregularities with peak-to-valley heights greater than about 10 microns and having cone-shaped elements. Haruyuki does not disclose

such features. More importantly, the Examiner's Answer continues to assert that Haruyuki must "inherently" disclose these features. Yet, it is noteworthy that to find the claimed "cone-shaped elements," the Examiner's Answer does not rely upon Haruyuki's own teachings or photographs. Rather, the Examiner's Answer continues to rely on the micrographs from Dr. Gubbi's Declaration that attempted to reproduce Haruyuki's examples. Examiner's Answer, p. 5. ,However, as shown in the second row of Exhibit 9, which compares Haruyuki's photographs with surfaces obtained during an attempt to duplicate Haruyuki's process, Haruyuki's examples cannot be reproduced. See Ex. 9. Thus, the rejection maintained in the Examiner's Answer is not based on the prior art's teaching, but rather, on the Applicants' Rule 1.132 submission that shows that Haruyuki's examples cannot be reproduced. See Examiner's Answer, p. 5.

With respect to Haruyuki's smoothening disclosure, the Examiner initially agrees that Haruyuki "teaches smoothening the surface on page 4 of the translation." Examiner's Answer, page 6. However, in the very next paragraph, the Examiner states that "'[s]moothness' is not explicitly discussed. Rather, only rough edges and pores sizes are discussed." *Id.* (emphasis added). Haruyuki does, in fact, explicitly discuss smoothness, stating that dipping in a mixed aqueous solution of HF and H_2O_2 in the posttreatment functions "to smooth the sharp edges or pointed ends formed on the ridgelines of the micro fine pits generated during the pretreatment." Ex. 5, page 4 (emphasis added).

The Examiner also states that he is not persuaded by Dr. Gubbi's experiments showing that the Appellants' surface have a different topography than those produced using Haruyuki's techniques. Specifically, the Examiner states, "the claimed invention is broader than any particular example," and "the Gubbi declaration failed to test the entire range of 1% to 6% HF, the entire range of 30 sec to 3 minutes, and the post treatment range of 1-6% HF, 1-10% H_2O_2, with the range of 10 to 60 seconds." Examiner's Answer, page 5, 7. There is no reasonable way,

however, that these entire ranges and combinations of ranges could have been tested. Instead, Dr. Gubbi took the very reasonable approach of trying to replicate Haruyuki's examples. Thus, the Appellants submit that MPEP § 716.02(d), which was cited in the Examiner's Answer, indeed applies in this instance. See Examiner's Answer, page 9; MPEP § 716.02(d) (stating "The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof.").

3. The Examiner's Answer Cannot Refute that Haruyuki and Niznick Teach Away from Their Combination.

Assuming, arguendo, that Haruyuki teaches the claim elements related to the acid-etched surface (which the Appellants submit is not the case), the question is whether Haruyuki can be combined with Niznick, which the Examiner's Answer alleges contains the other structural features of the claims. The Examiner asserts that Haruyuki does not teach away from Niznick because both references desire to promote "cell attachment and ongrowth." Examiner's Answer, page 7. The Examiner also asserts that "Niznick does not teach away from the claimed invention because it merely utilizes different roughness criteria from that of Haruyuki or Wennerberg." Examiner's Answer, page 8. The Examiner continues to ignore the fact that one skilled in the art would not combine Niznick with Haruyuki because of their insistence on vastly different degrees of roughness and Haruyuki's disclosure of the potentially grave hazards associated with Niznick's much greater degree of surface roughness.

With respect to this disclosure of Haruyuki, the Appellants disagree with the Examiner's statement that the Appellants' "analysis has exaggerated the statements of" Haruyuki. See Examiner's Answer, page 8. The Appellants have directly quoted Haruyuki's statement regarding the dangers of "an average depth in excess of 5 μm." See Appeal Brief, page 19. In

fact, the Appellants assert that it is the Examiner himself who has misconstrued Haruyuki's teaching by failing to consider the portion of Haruyuki immediately following (and part of the same sentence as) the portion quoted by the Examiner – that the tissue irritation that can be caused by depths in excess of 5 μm is "possibly a trigger for cancer." See Examiner's Answer, page 9; see also Ex. 5, page 4, column 1, lines 22-32.

Moreover, Niznick only discloses a surface texture of "25 microns or greater" for the threaded, middle region of its implants. See Ex. 7, column 5, lines 22, 44-45, column 7, lines 14, 44. In a preferred embodiment, Niznick actually states that "the surface must be roughened to at least 25 microns." Ex. 7, column 5, lines 44-45. Nowhere does Niznick teach average peak-to-valley distances of an implant surface texture below 25 microns, e.g., as an alternative embodiment. Thus, in view of both what Niznick does teach (exceedingly rough surfaces) as well as what Niznick does not teach (a threaded region surface roughness of less than 25 microns), the Appellants maintain that it is reasonable to infer that one skilled in the art reading Niznick would be motivated to create a surface roughness of less than 25 microns.

The Examiner also mischaracterizes the Appellants' arguments by stating that "[t]he Applicant argues that Niznick teaches a different roughness than that claimed. . . . However, Niznick was not utilized to meet that limitation of the claim language." Examiner's Answer, page 9. In actuality, the crux of the Appellants' argument is that Niznick teaches a different roughness than that taught by Haruyuki, with which the Examiner relies upon to meet that limitation of the claim language, and, thus, one would not combine Niznick with Haruyuki.

4. The Surfaces of Wennerberg Are Machined, Not Acid-Etched, as in the Present Claims

In response to the Appellants' argument that Wennerberg does not disclose acid-etched surfaces, the Examiner states that "the surfaces disclosed by Wennerberg meet the claim language pertaining to acid surfaces to the extent that such language can be given patentable

weight." Examiner's Answer, pages 7-8. The Appellants respectfully disagree and assert that the machined implant surfaces of Wennerberg are, in fact, very different from the surfaces of the present claims. Specifically, Wennerberg's implant surfaces do not have a roughened region having an acid etched surface produced after a native oxide layer has been removed from the threaded portion, as in the present claims. Rather, the surfaces of the implants of Wennerberg that the Examiner applies are machined. See Ex. 6, page 632 (stating that the small differences in the surface topography of the 3i Miniplant® and the Nobelpharma implants "may be explained by different manufacturing protocols and varying sharpness of the cutting tools.")

The Examiner's Answer suggests that it does not need to give "patentable weight" to the claim elements that specifically require an "acid-etched surface." Examiner's Answer, pages 7-8. It is unclear why the Examiner has chosen to ignore these positively recited characteristics (e.g., "acid-etched surface"). In any event, it is legally incorrect to simply discount those positively recited characteristics in the claims. In short, any reliance on Wennerberg for a teaching of the claimed surface is misplaced.

5. The Examiner's Answer Fails to Rebut the Applicants' Argument that Niznick Teaches Away from Having an Acid-Etched Surface in the Self Tapping Region, as Required by Independent Claims 63 and 68

Claims 63-67 are not obvious over the applied references for at least the reasons set forth above. Additionally, the Examiner's Answer does not address the Appellants' arguments set forth in the Appeal Brief regarding independent claim 63's recitation of a self-tapping feature of the dental implant and, specifically, that the acid-etched surface with the array of irregularities is located within the self-tapping feature. Niznick does not teach an acid-etched surface that extends along the threaded portion of the dental implant, into the self-tapping region, and to the lowermost end of the implant. Again, the middle threaded portion of Niznick's implant that is

roughened does not extend to the lowermost end of the implant or into the self-tapping region. In fact, Niznick states:

> For self-tapping insertion to be effective in dense bone, the cutting edges created by the grooves through the distal threads must be sharp enough to shave bone chips. Roughening the implant surface by grit-blasting, or by grit-blasting followed by coating the surface of the implant with a spray or molten titanium called Titanium Plasma Spray (TPS) or coating the surface with a bio-reactive material such as Hydroxylapatite (HA), rounds these cutting edges, decreasing the cutting efficiency of the self-tapping features.

Ex. 7, col. 1, ll. 53-62. Niznick also states:

> The threaded distal end of the implant is preferably uncoated and has a smooth enough surface to maintain sharp cutting threads for self-tapping insertion, thereby shortening surgical time and improving initial stability.

Id. at col. 4, ll. 44-48. As such, not only does Niznick not suggest the configuration of claims 63-67, it actually teaches away from it. Simply put, Niznick fails to overcome the deficiencies of Haruyuki and Wennerberg.

6. The Examiner's Answer Fails to Rebut the Appellants' Argument that the Prior Art Fails to Teach the Elements of Dependent Claims 61, 67, and 72

The Examiner's Answer also fails to refute the Appellants' arguments regarding dependent claims 61, 67, and 72. Thus, to reiterate, the Appellants contend that claims 61, 67, and 72 are separately patentable because not all of the elements of claims 61, 67, and 72 are taught in Haruyuki, Wennerberg, or Niznick. Specifically, each of these claims recite that the second acid solution (which produces the acid-etched surface) is a mixture of sulfuric and hydrochloric acids. Haruyuki only discloses an HF and H_2O_2 solution. Haruyuki's two-step process differs from that of the Appellants' process and, more importantly, differs in the appearance of the resulting surfaces. Ex. 8, ¶¶ H, K, N. Therefore, the claims that recite the acids used in the Appellants' two-step treatment are patentable over Haruyuki. Additionally,

neither Wennerberg nor Niznick provides any suggestion whatsoever that would lead one skilled in the art to utilize the inventions set forth in dependent claims 61, 67, and 72.

7. The Examiner's Answer Again Fails to Give Proper Consideration to the Porter Declaration Regarding Commercial Success

Regarding the Dr. Porter's Rule 1.132 Declaration, the Examiner argues that "the claimed product-by-process steps are quite broad such that they are not commensurate in scope with the process steps used to make Applicant's samples" and cites to MPEP § 716.02(d) for support for this argument. Examiner's Answer, page 9. However, MPEP § 716.02(d) is directed to the claim scope being commensurate with the testing for unexpected results. Dr. Porter's Rule 1.132 Declaration, on the other hand, proves the commercial success (not unexpected results) of the presently claimed invention. In other words, the Examiner has again failed to give due consideration to Dr. Porter's Rule 1.132 Declaration on commercial success in that the Examiner applied the wrong standard. MPEP § 716.03 (not MPEP § 716.02) discusses Rule 1.132 submissions to prove commercial success.

It is noted that the Examiner initially discounted Dr. Porter's Rule 1.132 Declaration because he was employed by the assignee. Of course, the best person to provide first-hand knowledge of the increased sales of a patented item is an employee of the assignee. How would a third party be able to provide this information? In any event, Dr. Porter's Rule 1.132 Declaration meets the requirements of MPEP § 716.03 and demonstrates the commercial success of the claimed invention.

The Appellants reiterate that the language of the Porter Declaration discussing the Osseotite® surface mirrors the language of the present claims. Ex. 10, page 4, ¶ 3, page 5, ¶ 5. The table below shows the congruence between the language of claim 51 and the language describing the Osseotite® surface in Dr. Porter's Declaration:

Language from Claim 51	Language from Paragraph 3 of Porter Declaration
"A dental implant made of titanium metal, comprising: . . ."	"The threaded implant is made of titanium . . ."
". . . a roughened region . . . being uniformly acid etched with a second acid solution . . ."	". . . and the resultant surface is etched with a combination of sulfuric and hydrochloric acids."
". . . after a native oxide layer had been removed by contact with a first acid solution . . ."	". . . prepared in accordance with a two-step, acid-etch treatment wherein the native oxide layer is substantially removed via hydrofluoric acid . . ."
". . . said roughened region including an array of irregularities having peak-to-valley heights not greater than about 10 microns."	"The resulting surface topography has . . . peak-to-valley heights of less than 10 microns."

The Osseotite® surface was further set forth in Exhibit A of the Porter Declaration, and several catalogs showing various examples of the overall screw-type structure of the dental implants having the Osseotite® surface were included as Exhibit B. Ex. 10. Thus, the Osseotite® dental implants discussed by Dr. Porter are undoubtedly covered by the claims that are the subject of this appeal.

8. Conclusion

For at least the reasons set forth above and previously submitted in the Appellants' Appeal Brief, the Appellants respectfully submit that the final rejection of claims 51 and 60-75 set forth in the Final Office Action mailed October 21, 2008, should be reversed.

Respectfully submitted,

Dated: November 2, 2009

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EXHIBIT 8

Customer No. 30223 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:	Atty. Docket No.: 47168-00035USC1
Richard J. Lazzara Thomas S. Heylmun Keith D. Beaty	Examiner: Paul Prebilic Group Art Unit: 3738
Application No.: 09/237,605	
Filed: January 25, 1999	
For: Infection-Blocking Dental Implant	

DECLARATION OF PRABHU GUBBI

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Prabhu Gubbi, declare that:

A. I reside at 4445 SW Oakhaven Lane, Palm City, FL 34990.

B. I have degrees in Mechanical Engineering and Foundry Engineering from Bangalore University, India. I also have a Ph.D. degree in Materials Engineering from Auburn University. Since receiving my Ph.D., I have been employed as an engineer with several corporations where I have worked as a materials scientist. Currently, I am a materials scientist with Implant Innovations, Inc ("*3i*").

C. In the course of my work at *3i*, I have examined numerous surfaces of objects used in dental implantology. One of the machines that I use to examine these surfaces is a Scanning Electron Microscope (SEM). The machine that I use is made by Aspex Instruments

LLC, Model No. PSEM II. Another machine used to measure surface roughness and surface area is a MicroXAM Surface Mapping Microscope (SMM) made by ADE Phase Shift, Model No. Micro XAM 100.

D. At the request of *3i*'s attorneys, I have carried out certain inspections of commercially pure titanium implants after they have been exposed to various treatments and compared the results with those of the methodology in the subject patent application, which is owned by *3i*. The results of this work are discussed below. In one series of tests (Exhibit A), a titanium dental implant was given a treatment according to the method described in this patent application to produce an Osseotite® surface, which is commercially available on *3i*'s dental implants. In the second series of tests (Exhibit B), titanium implants were exposed to the two-step procedure described in a Japanese published patent application, JP 3146679 A2 to Haruyuki. A third series of tests (Exhibit C) exposed titanium implants to a group of mineral acids. A fourth series of tests (Exhibit D) exposed titanium implants to a grit blasting step, followed by exposure to a group of mineral acids. I understand that my report is to be submitted to the U.S. Patent and Trademark Office in connection with the subject patent application.

First Test - Osseotite® Surface (Exhibit A)

E. A commercially pure titanium dental implant, after machining to form the implant's threaded shape, was first immersed in 8.45 wt% hydrofluoric acid for 60 seconds to remove the native oxide layer. After rinsing in deionized water with baking soda, followed by a rinse in deionized water, the implant was immersed in a mixture of one part by volume of 37 wt% hydrochloric acid and 7.5 parts by volume of 84.5 wt% sulfuric acid for 7 minutes at 60-70°C. The resulting surface is shown in Exhibit A, which includes an SEM photograph having a magnification of 2,000 times taken with the SEM machine and a three-dimensional

representation of the Osseotite® surface produced by the SMM machine adjacent to the SEM photograph. For comparison, the second sheet in Exhibit A includes an SEM photograph of the intermediate surface after using hydrofluoric acid to remove the native oxide (Stage I), and an SEM photograph after that intermediate surface has been further etched by the mixture of hydrochloric and sulfuric acids to achieve the Osseotite® surface (Stage II). As seen in these SEM photographs, the mixture of hydrochloric and sulfuric acids further roughens the intermediate surface after its native oxide was removed with hydrofluoric acid.

Second Test - Japanese Patent Application (Exhibit B)

F. A series of 4 mm diameter dental implants made of commercially pure titanium were taken from regular production after machining to form the implant, but before the implants had been provided with any type of treatment. Except for Comparative Example 1, each implant was dipped in hydrofluoric acid solutions using the conditions in the examples of the translation of the Japanese patent application, JP 3146679 A2, and recorded in Table "B" in the front of Exhibit B. Post-Treatment with mixtures of hydrofluoric acid and hydrogen peroxide was carried out where the examples used such post-treatments.

G. I photographed each implant after it was exposed to the treatments in the examples of the Japanese Patent Application using the SEM machine. SEM photographs having a magnification of 2000 times were taken of each implant and are shown in Exhibit B, identified by the example designations stated in the translation of JP 3146679 A2 at pages 5-6. In addition to the SEM photographs, the SMM machine was also used to examine each implant after the treatments, and the SMM representation of each surface is shown adjacent to the SEM photograph. A region of the surface measuring 162.8 μm by 123.3 μm was examined with the SMM machine. The area of this region would be 20,073 μm^2 if it were a flat plane. The

Comparative Example 1 was used as the base line for the area of the machined surface before pre-treatment and post-treatment. The Comparative Example 2 provides insight on the effect of only the pre-treatment step on the machined surface, since no post-treatment was performed in Comparative Example 2.

H. I conclude from the information provided in Table "B" that the maximum increase in the surface area was only 7.5%, which was found in the Experimental Example 2. From these SEM photographs and the three-dimensional representations of the surfaces, it appears that exposure of titanium implants to hydrofluoric acid treatments produced less roughening than reported by the Japanese Patent Application. In fact, the machining marks are still visible on many of the surfaces. Further, the post-treatment with hydrofluoric acid and hydrogen peroxide appears to smoothen the surface, which is consistent with the teaching at column 2 on page 4 of the translation of the Japanese Patent Application. Finally, the treatments of the Japanese patent application produced surfaces that do not resemble the surface achieved by the methodology of the subject patent application, as shown in Exhibit A.

Third Test - Mineral Acid Exposure (Exhibit C)

I. A series of 4 mm diameter dental implants made of commercially pure titanium were taken from regular production after machining to form the implant, but before the implants had been provided with any type of treatment. Each implant was dipped in a mineral acid solution having the concentration and temperature shown in Table "C," located at the front of Exhibit C.

J. I photographed each implant before and after it was exposed to the acid solution using the SEM machine. SEM photographs having a magnification of 2000 times are attached to Exhibit C. The SMM machine was also used to examine each implant before and after acid

treatment. A region of the surface measuring 162.8 μm by 123.3 μm was examined. The area of this region would be 20,073 μm^2 if it were a flat plane. The acid treatments had only a small effect on the surface area. In some cases, the area increased slightly and, in other cases, the area was reduced slightly. A reduction in surface area may be attributed to smoothing of the machining marks on the surface of the implants. The maximum increase in surface area was found to be 18.8%, produced by exposure to 49% HF for 5 minutes at 24°C (Test Sample 4). In that example, the machining marks are no longer visible and the titanium metal grains can be seen on the surface.

K. I conclude from the information provided in Exhibit C that exposure of machined titanium implants to the mineral acids produced little effect, except for hydrofluoric acid, which produced a surface in which the grain structure could be seen. None of the acids were capable of providing a surface roughness of twice the initial value (*i.e.,* 100%). Furthermore, the mineral acids produced surfaces that do not resemble the surface achieved by the methodology of the subject patent application, as shown in Exhibit A.

Fourth Test - Grit Blast Plus Mineral Acid Exposure (Exhibit D)

L. A second series of 4 mm dental implants made of commercially pure titanium was taken from regular production after machining to form the implant, but before the implants were provided with any further treatment. Each implant was subjected to grit blasting by Biocoat, Inc., using aluminum oxide #60 grit at a pressure of 20-60 psig. Thereafter, each grit blasted implant was dipped in an acid solution having the same concentration and at the same temperature as used in the Third Tests (Exhibit C) mentioned above. After remaining in the acid solution for the length of time stated in Table "D," which is at the front of Exhibit D, each implant was rinsed in reverse osmosis/deionized water, isopropyl alcohol and dried with a hot air gun.

M. I took photographs of each grit-blasted implant before and after it was exposed to the acid solution using the SEM machine. SEM photographs having a magnification of 2000 times are attached to Exhibit D. The SMM machine was also used to examine each implant before and after acid treatment. A region of the surface measuring 162.8 μm by 123.3 μm was examined. The area of this region would be 20,073 μm^2 if it were a flat plane. It is evident that the grit blasting increased the area significantly, compared to the surface of machined implants. The grit-blasted surface area was increased by acid treatment in some cases and decreased in others, with the maximum increase being 10.7% after exposure to nitric acid (Test Sample 1) and the maximum decrease on surface area being 34.4% after exposure to hydrofluoric acid (Test Sample 4). In no case did the acid exposure increase the surface area by a factor of two (*i.e.*, 100%).

N. I conclude that the exposure of the grit-blasted implant surfaces to these mineral acids did not produce a surface resembling the surface shown in the photographs of the subject patent application, as shown in Exhibit A.

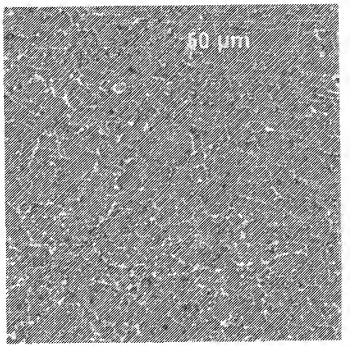
O. The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this Declaration, declares that the facts set forth in this Declaration are true, and all statements made of this own knowledge are true, and all statements made on information and belief are believed to be true.

Date: 05-23-2003

Prabhu Gubbi

EXHIBIT A

Exhibit A: Osseotite SEM and 3-D Surface Map



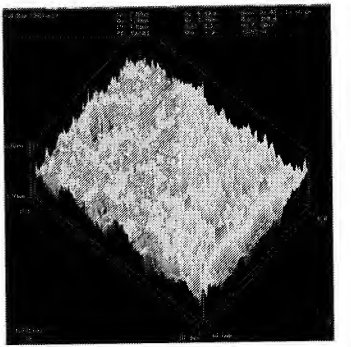
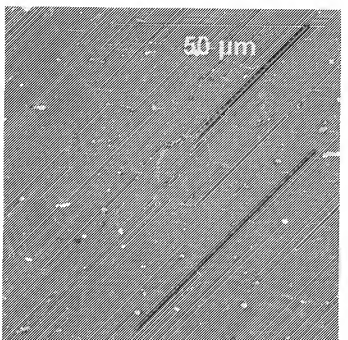
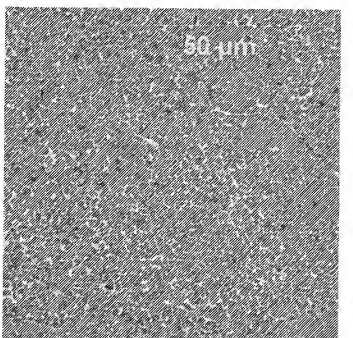


Exhibit A: SEMS after HF, and after Mixture of H_2SO_4 + HCl



Stage I. After Etching in HF



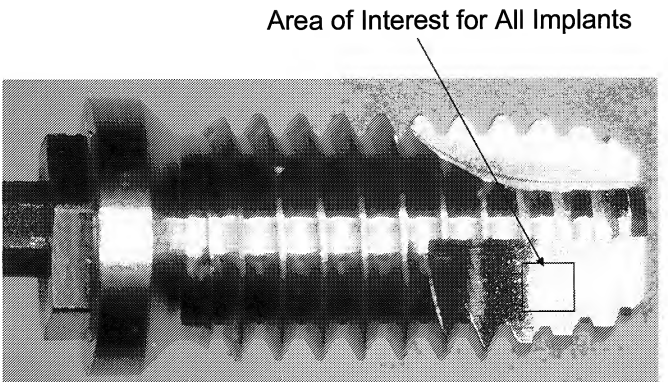
Stage II. After Etching in HF and Etching in H_2SO_4 + HCl

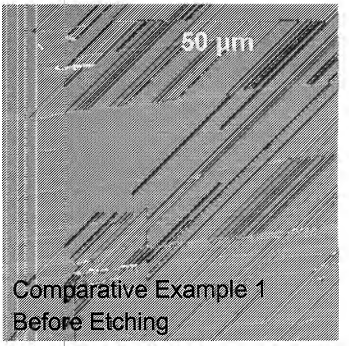
EXHIBIT B

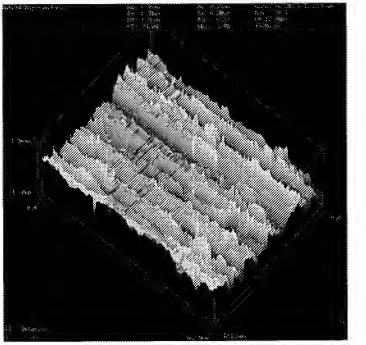
Table B. Results of Tests Conducted According To JP 3146679 A2

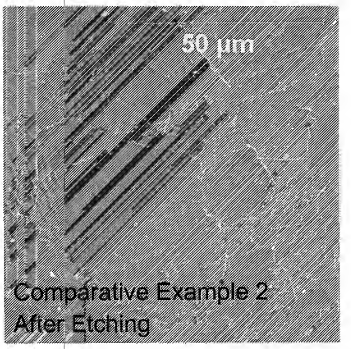
Test Sample No.	Pre-Treatment and Post-Treatment Conditions	Surface Area Before Pre & Post-Treatment (μm^2)	Surface Area After Pre & Post-Treatment* (μm^2)
Comparative Example 1	No Pre-Treatment No Post-Treatment (i.e, Machined Surface)	21110.36	N/A
Comparative Example 2	Pre-Treatment: 4% HF, 1 min., No Post-Treatment	21110.36	22660.69* *Surface Area after Pre-Treatment, No Post-Treatment
Example 1	Pre-Treatment: 4% HF, 30 sec. Post-treatment: 4% HF + 8% H2O2, 15 sec.	21110.36	21791.26
Example 2	Pre-Treatment: 4% HF, 1 min. Post-treatment: 4% HF + 8% H2O2, 15 sec.	21110.36	21992.64
Example 3	Pre-Treatment: 4% HF, 2 min. Post-treatment: 4% HF + 8% H2O2, 15 sec.	21110.36	22201.61
Example 4	Pre-Treatment: 2% HF, 1 min. Post-treatment: 4% HF + 8% H2O2, 15 sec.	21110.36	21820.26
Example 5	Pre-Treatment: 8% HF, 1 min. Post-treatment: 4% HF + 8% H2O2, 15 sec.	21110.36	22325.15
Experiment Example 1	Pre-Treatment: 4% HF, 1 min. Post-treatment: 8% H2O2, 1 min.	21110.36	22694.75
Experiment Example 2	Pre-Treatment: 4% HF, 1 min. Post-treatment: 8% H2O2, 15 sec.	21110.36	22148.67

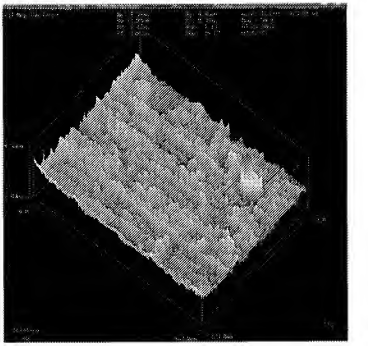
Scanning Electron Microscopy and Surface Mapping Microscopy Investigation on Implants

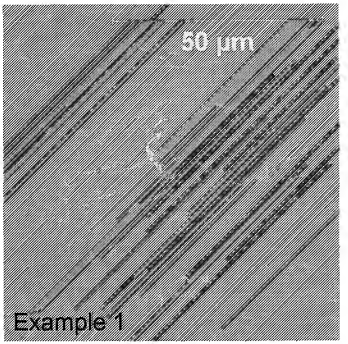


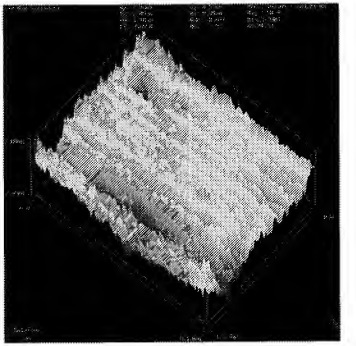

50 µm
Comparative Example 1
Before Etching

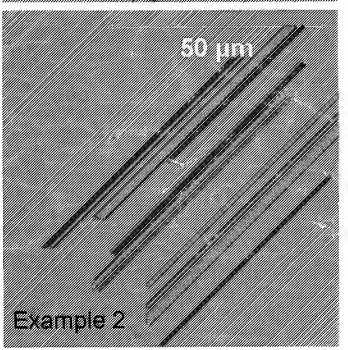


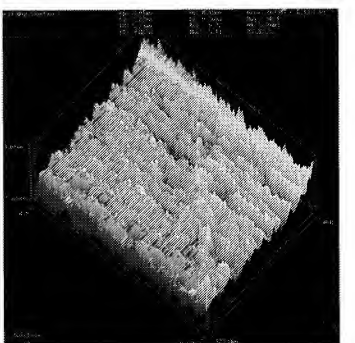

50 µm
Comparative Example 2
After Etching

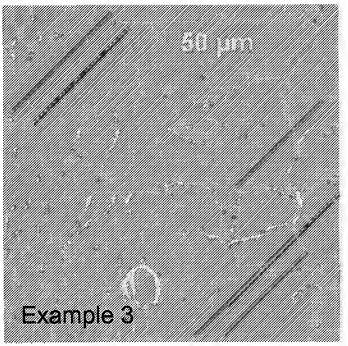


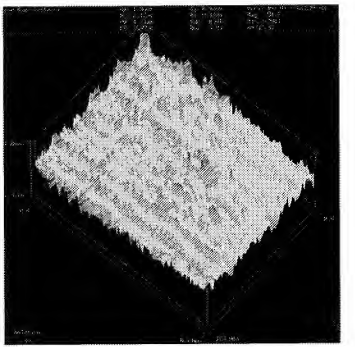

50 µm
Example 1

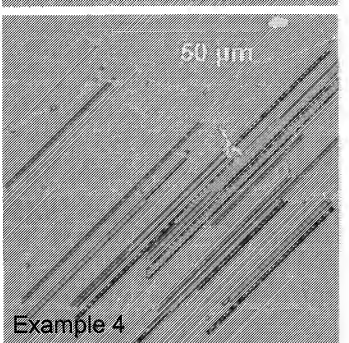


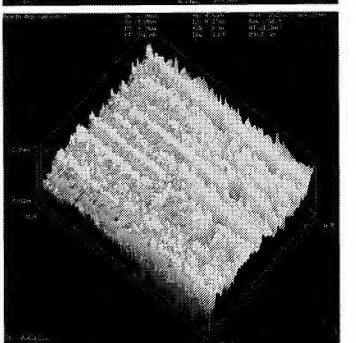

50 µm
Example 2

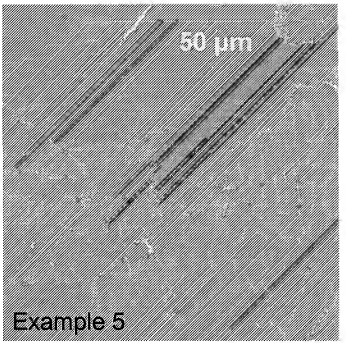


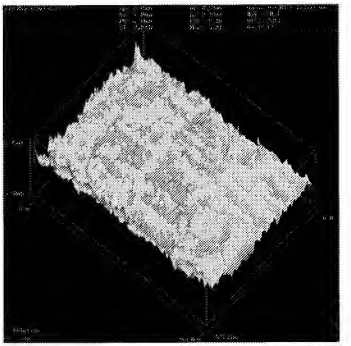

50 µm
Example 3

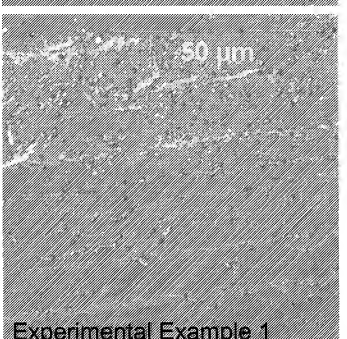


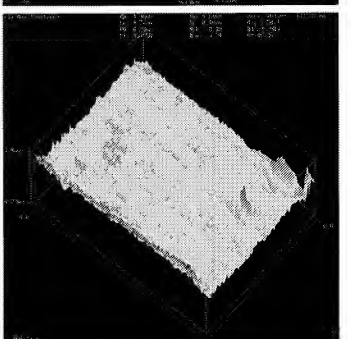

50 µm
Example 4

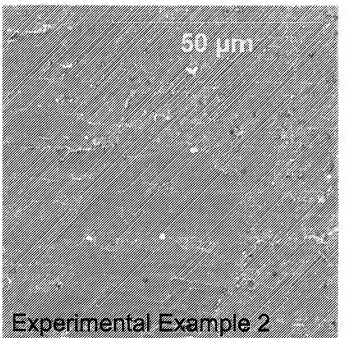



50 μm
Example 5




50 μm
Experimental Example 1





Experimental Example 2

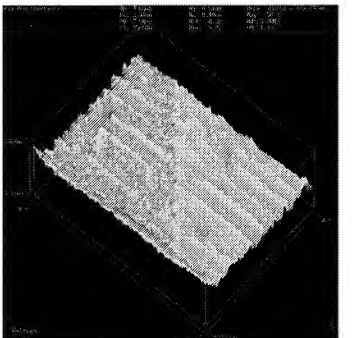


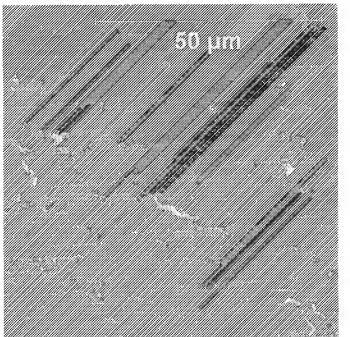
EXHIBIT C

Table C: Results of Etching Machined Surface with Various Mineral Acids

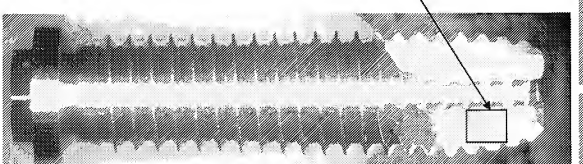
Test Sample No.	Etching Conditions	Surface Area Before Etching (μm^2)	Surface Area After Etching (μm^2)
1	70% Nitric Acid, 5 min. at 24°C	20396.93	20583.66
2	85% Phosphoric Acid, 5 min. at 24°C	20999.55	20314.00
3	96% Sulfuric Acid, 5 min. at 24°C	22019.00	20405.75
4	49% Hydrofluoric Acid, 5 min. at 24°C	20440.97	24289.25
5	37% Hydrochloric Acid, 5 min. at 24°C	20433.19	20274.46
6	70% Nitric Acid, 5 min. at 50-55°C	20845.00	20409.54
7	85% Phosphoric Acid, 5 min. at 50-55°C	20699.07	21270.39
8	96% Sulfuric Acid, 5 min. at 50-55°C	20847.20	20347.88

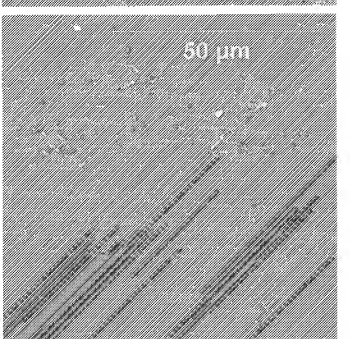
Test Sample # 1

Before Etching



Area of Interest

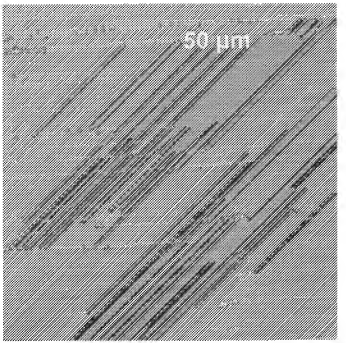




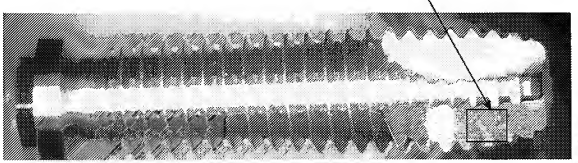
After Etching

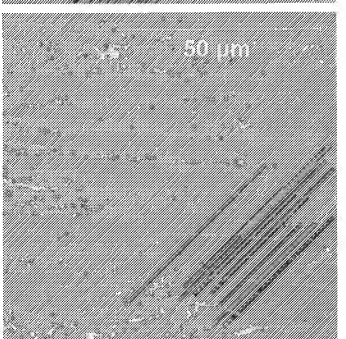
Test Sample # 2

Before Etching



Area of Interest

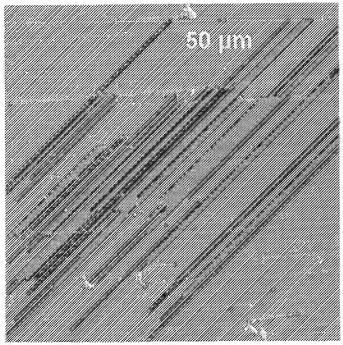




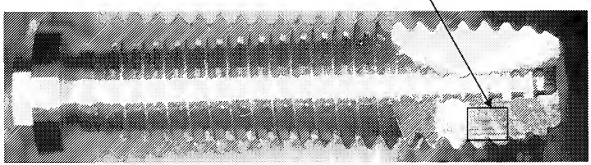
After Etching

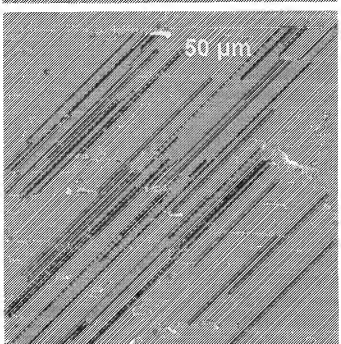
Test Sample # 3

Before Etching



Area of Interest



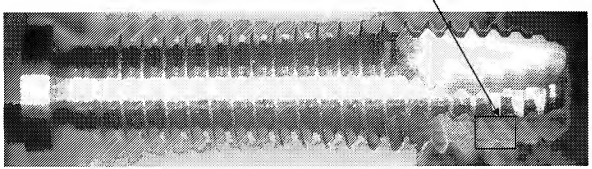


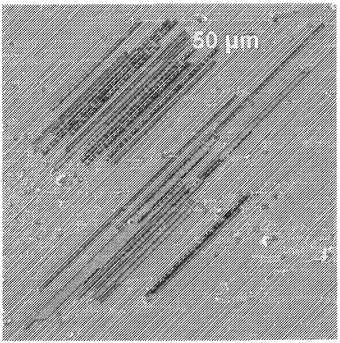
After Etching

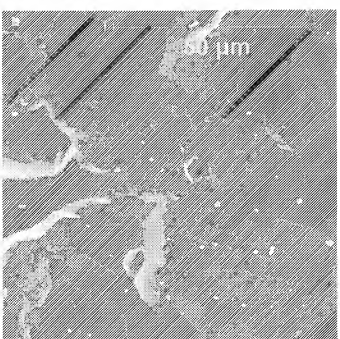
Test Sample # 4

Before Etching

Area of Interest





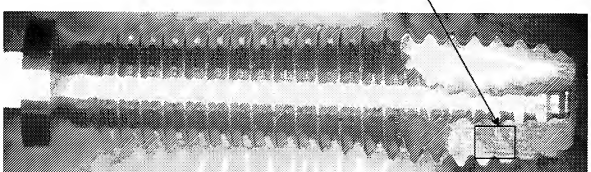


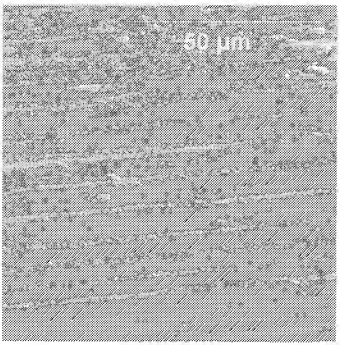
After Etching

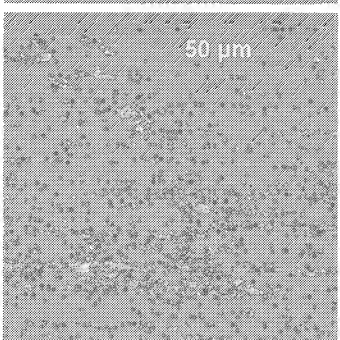
Test Sample # 5

Before Etching

Area of Interest





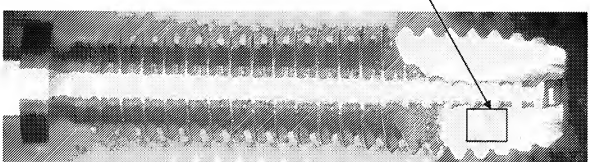


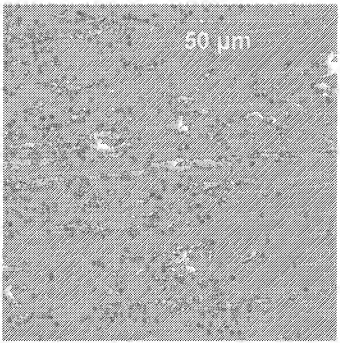
After Etching

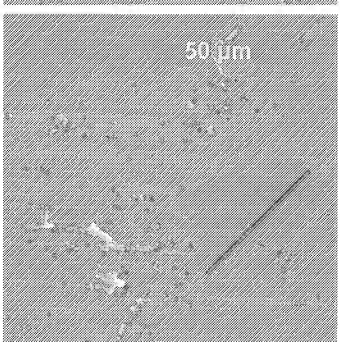
Test Sample # 6

Before Etching

Area of Interest





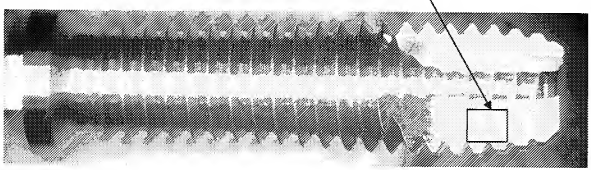


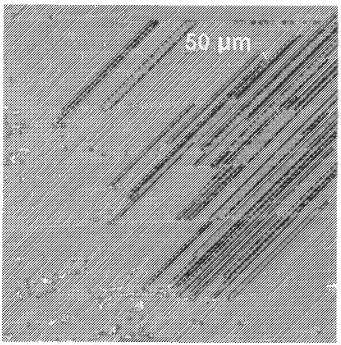
After Etching

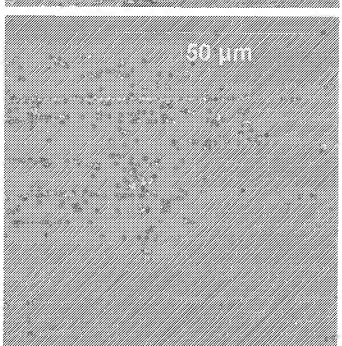
Test Sample # 7

Before Etching

Area of Interest





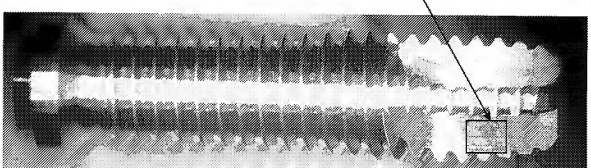


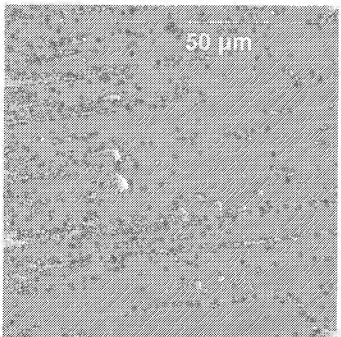
After Etching

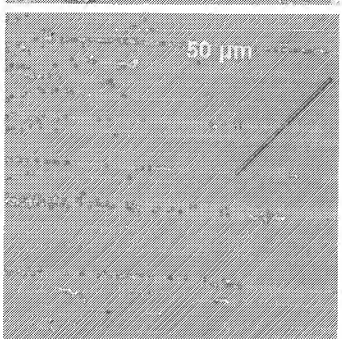
Test Sample # 8

Before Etching

Area of Interest







After Etching

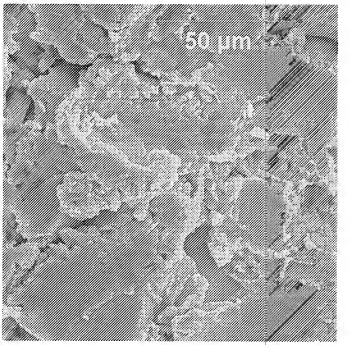
EXHIBIT D

Table D: Results Of Etching Grit-Blasted Surface with Various Mineral Acids

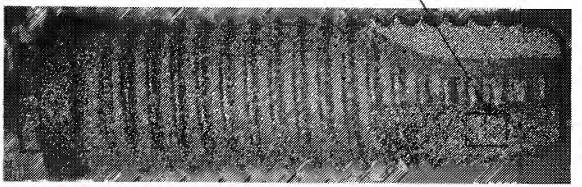
Test Sample No.	Etching Conditions	Grit-Blasted Surface Area Before Etching (im^2)	Surface Area After Etching (im^2)
1	70% Nitric Acid, 5 min. at 24°C	29509.84	32666.07
2	85% Phosphoric Acid, 5 min. at 24°C	38307.96	29186.49
3	96% Sulfuric Acid, 5 min. at 24°C	30936.96	26998.21
4	49% Hydrofluoric Acid, 5 min. at 24°C	33771.91	22157.74
5	37% Hydrochloric Acid, 5 min. at 24°C	35737.09	37123.01
6	70% Nitric Acid, 5 min. at 50-55°C	36612.49	38678.22
7	85% Phosphoric Acid, 5 min. at 50-55°C	31222.55	32272.19
8	96% Sulfuric Acid, 5 min. at 50-55°C	34272.34	35174.25

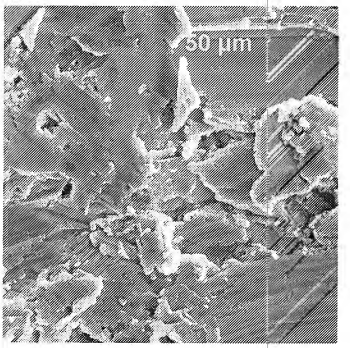
Blasted Test Sample # 1

Before Etching



Area of Interest

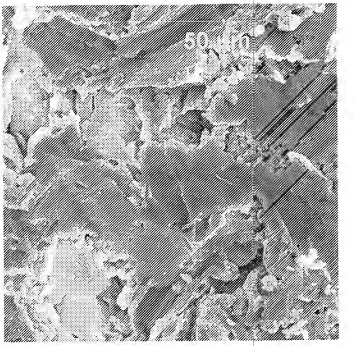




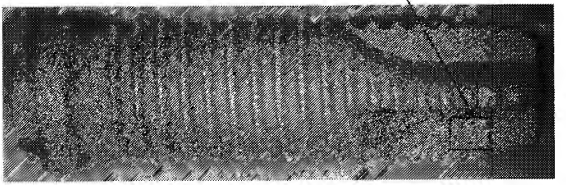
After Etching

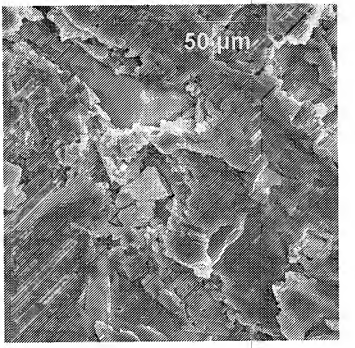
Blasted Test Sample # 2

Before Etching



Area of Interest

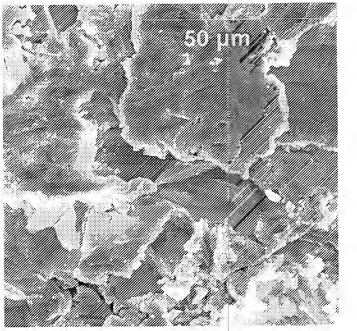




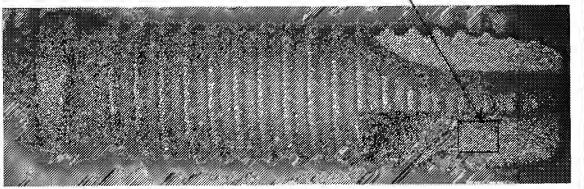
After Etching

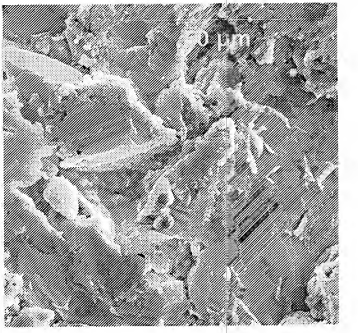
Blasted Test Sample # 3

Before Etching



Area of Interest



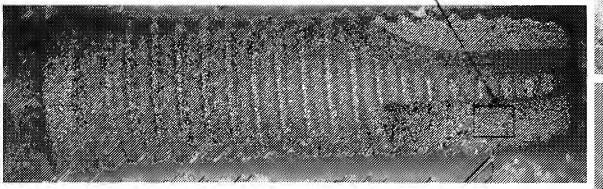


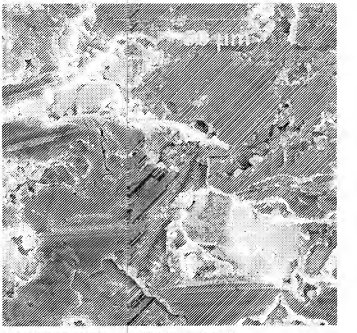
After Etching

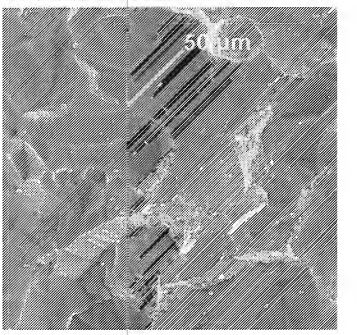
Blasted Test Sample # 4

Before Etching

Area of Interest



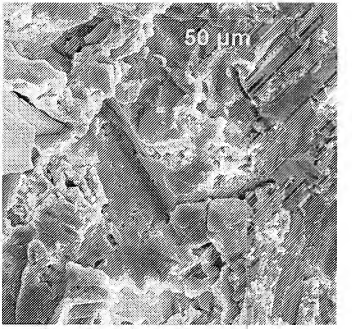




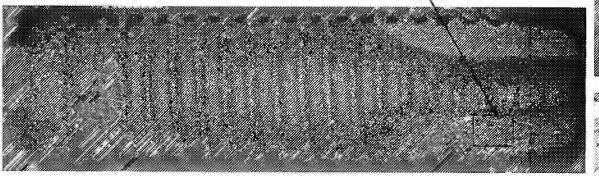
After Etching

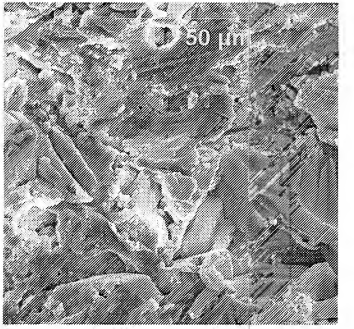
Blasted Test Sample # 5

Before Etching



Area of Interest

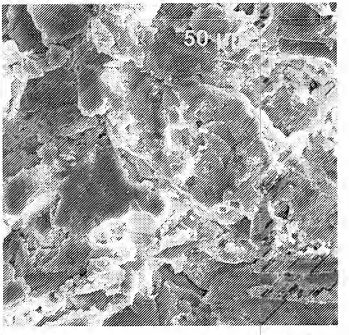




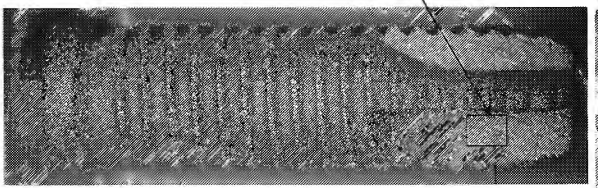
After Etching

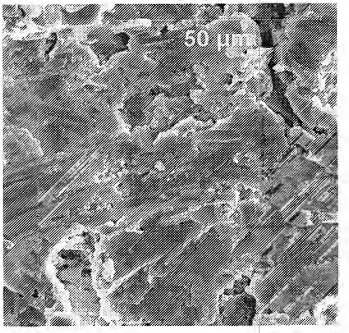
Blasted Test Sample # 6

Before Etching



Area of Interest

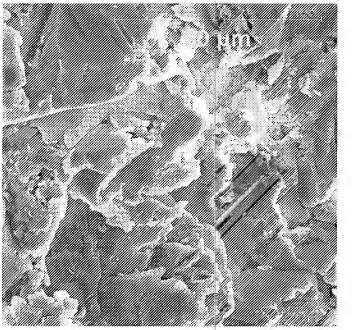




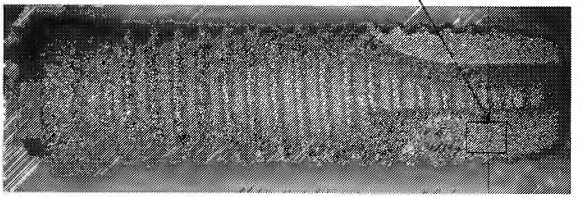
After Etching

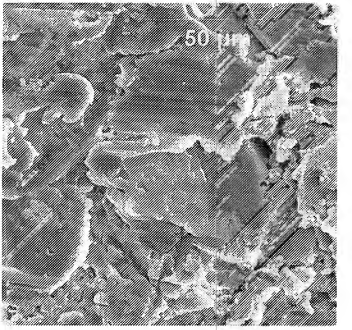
Blasted Test Sample # 7

Before Etching



Area of Interest



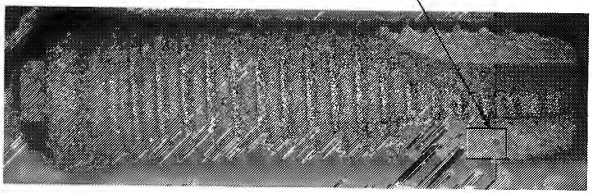


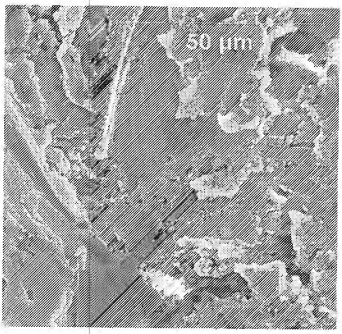
After Etching

Blasted Test Sample # 8

Before Etching

Area of Interest





After Etching